



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,434	02/28/2001	Wilfried Fischer	2727-130	5919

7590

01/09/2003

RONALD R. SANTUCCI
745 FIFTH AVENUE
NEW YORK, NY 10151

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,434

Applicant(s)

FISCHER, WILFRIED

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,8,10-15 and 17-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,8,10-15 and 17-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Request for Reconsideration received October 30, 2002 is acknowledged. Claims 1, 3-5, 8, 10-15, and 17-32 are included in the prosecution of this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Rejections of claims 1, 3, 5, 8, 10-15, and 17-32 under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172 in combination with WO 89/07959, is maintained.

Response to Arguments

Applicant argues that instant invention addresses the problem of providing for an inexpensive matrix and meets the requirements of the body's time dependent need for active ingredients. Applicant argues that WO 95/24172 does not disclose or even suggest a skilled artisan to have a hydrophobic solvent or provide for perforations. Applicant argues that WO 89/07959 does not address the body's time dependent need for active ingredients. It is argued That WO '959 relates to a microporous membrane used to define a cavity between a physiologically active substance in liquid form. Instead the instant invention is a perforated polymer layer.

Applicant's arguments have been fully considered but they are not persuasive. As discussed in the rejection set forth in the office action dated July 25, 2002, WO '172 lacks only in exemplifying the recited active solution that is immiscible with water and teachings of perforations in the transdermal art. The examiner points to page 19, lines

17-35 where WO '172 teaches mixing nicotine with an antioxidant such as BHT, EDTA, or tocopherol. Further, the nicotine, antioxidant, and water-soluble polymer make-up the active layer. The examiner points out that tocopherol is not miscible with water.

Additionally, on page 8 WO '172 teaches dissolving or dispersing the drug in a selected solvent such as a semi-solid low molecular weight polymer, wax, or petroleum jelly. WO teaches rate control of the drug on page 18. The examiner relies on WO '959 to teach the rate-controlling effect of a combined hydrophobic and hydrophilic solvent. Secondly, the examiner relies on the secondary reference to specifically teach the use of porous polymer layer, which as demonstrated by the WO, is an obvious skill in the transdermal art. Firstly, although the reference refers to the layer as a microporous membrane layer, this layer is in fact a microporous polymer layer as seen on page 7, lines 19. One would be motivated to look to WO '959 since the reference teaches the use of porous polymers control the rate of diffusion of the drug and interaction between layers in the device (page 11). Further, one would expect similar results since both teach a controlled release device of administering nicotine. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., body's time dependent need for active ingredients) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Rejection of claim 4 under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172 in combination with WO 89/07959 in view of Wick et al (5679373), is maintained.

Response to Arguments

Applicant argues that Wick relates to melt-blending an active agent matrix polymer.

Applicant's arguments have been fully considered but they are not persuasive. The examiner relies on Wick et al *only* to teach the equivalence of methylcellulose and gelatin as water-soluble polymers for use in transdermals. A skilled artisan would expect similar results since Wick teaches water-soluble polymers for use in the transdermal art.

Rejection of claim 32 under 35 U.S.C. 103(a) as being unpatentable over WO 95/24172 in combination with WO 89/07959 in view of Place et al (5242391), is maintained.

Response to Arguments

Applicant argues that Place relates to treatment of erectile dysfunction.

Applicant's arguments have been fully considered but they are not persuasive. The examiner relies on Place et al to teach the use of nitroglycerin or testosterone to treat impotence; therefore providing motivation for one of ordinary skill in the art to combine the recited drugs in instant claim 32. Further, on column 4, lines 28, Place teaches the combination of two or more drugs act synergistically.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 703-305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

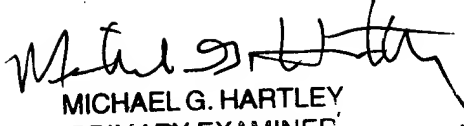
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 709-3080196.

Application/Control Number: 09/700,434
Art Unit: 1616

Page 6

SSG
~~SSG~~

January 2, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER